

REMARKS

Claim Amendments

Claims 1-59 are pending. Claims 2, 6, 14-46 and 48 are canceled without prejudice or disclaimer. Claims 1, 3, 13, 50, 53, 55 and 59 have been amended to correct the designation for the alpha 5 beta 1 integrin in order to better clarify the invention. Support for the amendments can be found throughout the specification and in particular on page 18, paragraph [0064] and also on page 22, paragraph [0080]. Applicants have also amended paragraph numbers [0003], [0011], [0013], [0021], [0022], [0023], [0024], [0064], [0079], [0080], [0082], [0087], and [0125], which refer to the alpha 5 beta 1 integrin, to be consistent with the language in the claims as amended. No new matter has been entered by way of this amendment. Accordingly, claims 1, 3-5, 7-13, 47 and 49-59 are pending.

Restriction Requirement

The Examiner has required restriction to one of the following inventions under 35 U.S.C. §121 and 372.

- Group I. Claims 1-5 and 7-11, drawn to a method for disrupting survival signaling from the microenvironment to cancer cells.
- Group II. Claims 12, 13, 47, 49-54, drawn to a method of inhibiting cellular proliferation or inducing cell death or cellular differentiation or for treating a cancer or a hyperproliferative disorder in a mammal.
- Group III. Claims 55-59, drawn to a pharmaceutical composition.

The Examiner also alleges that this application contains claims directed to more than one species of the generic invention. The Examiner alleges that these species are deemed to lack unity of invention because they are not so linked as to form a single general inventive concept under PCT Rule 13.1.

The species are as follows:

If any Group is elected, applicant must elect one species from the following groups.

Integrin: (claims 3, 13, 50, 53, 55, 59)

- 1) alpha 5
- 2) beta 1

Cancer cell: (claims 4 and 49)

- 3) breast
- 4) prostate

Agent: (claims 5-8, 56)

- 5) antibody specific for an integrin
- 6) blocking peptide
- 7) modified peptide
- 8) all trans retinoic acid
- 9) retinoic acid derivative
- 10) kinase inhibitor
- 11) transcription inhibitor

If applicant elects number 10) kinase inhibitor from the agent species list above, applicant must further elect a kinase inhibitor.

Kinase inhibitor: (claims 11, 52 and 58)

- 19) LY294002
- 20) UO 126
- 21) AG82
- 22) Y27632
- 23) SB203580
- 24) PD169316
- 25) PD98059
- 26) RO218220
- 27) C3 transferase inhibitor

If Group I or II is elected, a further "inhibitor administration" species must be elected.

Inhibitor administration: (claims 47, 53 & 59)

- 28) prior to a chemotherapeutic agent or radiation therapy
- 29) concurrent with a chemotherapeutic agent or radiation therapy.

Applicant is required, in reply to this action, to elect a single species to which the claims shall be restricted if no generic claim is finally held to be allowable. The Examiner notes that the following claims are generic: 1, 5, 9, and 12.

Responsive to the Requirement for Restriction, Applicants elect to prosecute the invention of Group I, claims 1-5 and 7-11, drawn to a method for disrupting survival signaling from the microenvironment to cancer cells, with traverse. With respect to the election of species, Applicants elect the following:

1. **Regarding alpha 5 and beta 1 (claims 3, 13, 50, 53, 55 and 59),**
Applicants would like to thank Examiner Meera Natarajan for a telephonic discussion held on March 21, 2007, whereby Applicants' Representative, Veronica Mallon, explained to the Examiner that since the alpha 5 beta 1 integrin exists as a dimer, it was Applicants' intention to claim the dimeric form of the molecule, not the individual alpha or beta subunits. Support for this can be found in the Examples, and in particular, on page 18, paragraph [0064]. Moreover, Applicants have amended the claims to delete "alpha 5 **or** beta 1". The claims now recite "alpha 5 beta 1" and the relevant paragraphs of the specification have been corrected to reflect this change. As such, the Examiner was in agreement that these changes would better clarify what Applicants' intention was, and that there was no need to elect a species from either alpha 5 or beta 1.
2. **Regarding the cancer cell (claims 4 and 49),** Applicants elect number 3) breast cancer cells, without traverse.
3. **Regarding the agent (claims 5-8 and 56),** Applicants elect number 6) blocking peptide, without traverse.
4. **Regarding inhibitor administration (claims 47, 53 and 59),**
Applicants elect number 28) prior to a chemotherapeutic agent or radiation therapy, without traverse.

Applicants respectfully request reconsideration of the Requirement for Restriction, or in the alternative, modification of the Restriction Requirement to allow prosecution of more than one group of Claims designated by the Examiner in the present Application, for the reasons provided as follows.

Under 35 U.S.C. §121 "two or more independent and distinct inventions ... in one Application may ... be restricted to one of the inventions." Inventions are "'independent'" if "there is no disclosed relationship between the two or more subjects disclosed" (MPEP 802.01). The term "'distinct'" means that "two or more subjects as disclosed are related ... but are capable of separate manufacture, use or sale as claimed, AND ARE PATENTABLE OVER EACH OTHER" (MPEP 802.01) (emphasis in original). However, even with patentably distinct inventions, restriction is not required unless one of the following reasons appear (MPEP 808.02):

1. Separate classification
2. Separate status in the art; or
3. Different field of search.

Further, under Patent Office Examining Procedures, "[i]f the Search and Examination of an entire Application can be made without serious burden, the Examiner must examine it on the merits, even though it includes claims to distinct or independent inventions" (MPEP 803, Rev. 8, May 1988) (emphasis added).

Applicants respectfully submit that the groups designated by the Examiner fail to define methods with properties so distinct as to warrant separate Examination and Search. Claims 1-5 and 7-11 of elected Group I, are drawn to methods for disrupting survival signaling from the microenvironment to cancer cells, and are fundamentally related to Claims 12, 13, 47 and 49-54 of Group II, drawn to methods of inhibiting cellular proliferation or inducing cell death or cellular differentiation or for treating a cancer or a hyperproliferative disorder in a mammal.

Applicants respectfully assert that the search for any of the characteristics of the methods separately classified by the Examiner as the invention of Group I would require an additional search of the related classes wherein the invention of Group II are classified, thus resulting in a duplicate search for the same or related material.

Accordingly, Applicants submit that the Search and Examination of Group II with elected Group I can be made without serious burden, and therefore respectfully request that the Examiner examine the claims of Group II with elected Group I.

In summary, Applicants respectfully submit that conjoint examination of Groups I and II in the present Application would not present an undue burden on the Examiner, and accordingly, request withdrawal of the Requirement for Restriction to the extent that these groups be rejoined.

In view of the above, withdrawal of the Requirement for Restriction is requested, and an early action on the merits of the claims is courteously solicited.

Fees

No fees are believed to be necessitated by the instant response. However, should this be in error, authorization is hereby given to charge Deposit Account No. 11-1153 for any underpayment, or to credit any overpayments.

Respectfully submitted,



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